COVID-19 vaccination in pregnancy, paediatrics, immunocompromised patients, and persons with history of allergy or prior SARS-COV-2 infection: overview of current recommendations and pre- and post-marketing evidence for vaccine efficacy and safety

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As of July 22, 2021 the following international/national scientific society and regulatory agencies were searched:

- European Medicines Agency. COVID-19 vaccine Spikevax approved for children aged 12 to 17 in EU. 2021. Available from: <a href="https://www.ema.europa.eu/en/news/covid-19-vaccine-spikevax-approved-children-aged-12-17-eu">https://www.ema.europa.eu/en/news/covid-19-vaccine-spikevax-approved-children-aged-12-17-eu</a>
- European Medicines Agency. EMA commissions independent research to prepare for real-world monitoring of COVID-19 vaccines. 2020. Available from:
   <a href="https://www.ema.europa.eu/en/news/ema-commissions-independent-research-prepare-real-world-monitoring-covid-19-vaccines">https://www.ema.europa.eu/en/news/ema-commissions-independent-research-prepare-real-world-monitoring-covid-19-vaccines</a>
- European Medicines Agency. First COVID-19 vaccine approved for children aged 12 to 15 in EU. 2021. Available from: <a href="https://www.ema.europa.eu/en/news/first-covid-19-vaccine-approved-children-aged-12-15-eu">https://www.ema.europa.eu/en/news/first-covid-19-vaccine-approved-children-aged-12-15-eu</a>

- The American College of Obstetricians and Gynecologists. COVID-19 Vaccination
   Considerations for Obstetric–Gynecologic Care. 2021. Available from:
   <a href="https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care">https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care</a>
- Royal College of Obstetricians & Gynaecologists. COVID-19 vaccines, pregnancy and breastfeeding. 2021. Available from: <a href="https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/">https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/</a>
- The Royal Australian and New Zeland College of Obstetricians and Gynaecologists.

  Pregnant women are now eligible for the Pfizer COVID-19 vaccine. 2021. Available from: <a href="https://ranzcog.edu.au/news/pregnant-women-are-now-eligible-for-the-pfizer-cov">https://ranzcog.edu.au/news/pregnant-women-are-now-eligible-for-the-pfizer-cov</a>
- Società Italiana di Ginecologia e Ostetricia. Gravidanza e Vaccinazione anti COVID. 2021.
   Available from: <a href="https://www.sigo.it/wp-content/uploads/2021/05/PositionPaper Gravidanza Vaccinazione anti COVID 05.05.20">https://www.sigo.it/wp-content/uploads/2021/05/PositionPaper Gravidanza Vaccinazione anti COVID 05.05.20</a>
   21.pdf
- European Medicines Agency. COVID-19 Vaccine Janssen. 2021. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen
- European Medicines Agency. Comirnaty. 2021. Available from: <a href="https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty">https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty</a>
- European Medicines Agency. Spikevax (previously COVID-19 Vaccine Moderna). 2021. Available from: <a href="https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna">https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna</a>
- European Medicines Agency. Vaxzevria (previously COVID-19 Vaccine AstraZeneca). 2021. Available from: <a href="https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca">https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca</a>
- American College of Rheumatology Guidance for COVID-19 Vaccination in Patients With Rheumatic and Musculoskeletal Diseases. Available from: <a href="https://www.rheumatology.org/Practice-Quality/Clinical-Support/COVID-19-Guidance">https://www.rheumatology.org/Practice-Quality/Clinical-Support/COVID-19-Guidance</a>
- American College of Allergy, Asthma & Immunology. ACAAI Updates to Guidance on Risk of Allergic Reactions to COVID-19 Vaccines. 2021. Available from: <a href="https://acaai.org/news/acaai-updates-guidance-risk-allergic-reactions-covid-19-vaccines">https://acaai.org/news/acaai-updates-guidance-risk-allergic-reactions-covid-19-vaccines</a>
- AIFA. FAQ COVID-19 vaccines. 2021. Available from: https://www.aifa.gov.it/en/domande-e-risposte-su-vaccini-covid-19
- European Medicines Agency. Monitoring of COVID-19 medicines. 2021. Available from: <a href="https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/monitoring-covid-19-medicines-0">https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/monitoring-covid-19-medicines-0</a>